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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,151	05/18/2006	George C. Prendergast	3882-P03161US2	4302

110 7590 01/11/2011

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1601 MARKET STREET
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EXAMINER	
STONE, CHRISTOPHER R	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
01/11/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,151	PRENDERGAST ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER R. STONE	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-40,43-47 and 55-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *38-40, 43-47, 55 and 56* is/are allowed.

6)☒ Claim(s) *57-65* is/are rejected.

7)☒ Claim(s) *66* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/26/2010, 11/24/2010*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed November 24, 2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 38-40, 43-47 and 55-66 are pending. Methyl-TH-DL-Trp, 1-methyl-DL-tryptophan (1MT) and cisplatin are the elected species of IDO inhibitors and chemotherapeutic compound currently under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 57-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munn et al (US PGPUB 2001/0001040) in view of Hausheer et al (US 5,902,610)

Claims 57-65 are drawn to a method of treating cancer comprising administering an IDO inhibitor and a chemotherapeutic agent. Methyl-TH-DL-Trp, 1-methyl-DL-tryptophan (1MT) and cisplatin are the elected species of IDO inhibitors and chemotherapeutic compound currently under examination.

Munn et al teaches that IDO inhibitors, including 1MT, are useful in the treatment of cancer (paragraph [0017]). Munn et al does not teach the administration of cisplatin with 1MT. Hausheer et al teaches that cisplatin is a widely used anticancer agent used in combination with other anticancer agents in the treatment of a broad spectrum of cancers, including e.g. breast, lung, head and neck, ovary, etc. (column 3, lines 32-39). Hausheer et al further teaches that additional anticancer agents can be administered prior to, simultaneously or following the administration of cisplatin in combination therapies (column 1, lines 11-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to administer 1MT and cisplatin, concurrently or sequentially, in any order, to treat cancers, including breast, lung, head and neck, ovary, etc., since both compounds were known to be useful chemotherapeutic agents, thus resulting in the instantly claimed invention with a reasonable expectation of success.

Response to Arguments

A showing of unobviousness must be commensurate in scope with the claims which the evidence is offered to support. To warrant the allowance of generic claims, the showing of unobviousness must include enough examples to be reasonably representative of the genus. Although objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support, the probative value of a narrow range of date can be reasonably extended to prove the unobviousness of a broader claimed range when one could ascertain a trend in the exemplified data which would allow him to reasonably extend the probative values thereof. In re Clemens et al. 206 USPQ 289 (CCPA 1980). In re Kollman et al. 201 USPQ 193 (CCPA 1979).

For instance, in the instant case with regard to alleged unexpected synergy, Applicant would have to provide data or other evidence that a synergistic result would be reasonably expected to be observed across physiologically and etiologically distinct cancer species encompassed by the genus cancer.

In the instant case Applicant has provided evidence of an unexpected synergistic anti-cancer activity of the instantly claimed method (i.e. the combination therapy of 1MT and cisplatin) in the treatment of a single specie of cancer, i.e. breast cancer (Fig. 5). Applicant has provided no evidence that the instantly claimed combination would exhibit unexpected synergistic anti-cancer activity in other species of cancer. Given the unexpected nature of synergy in general as well as the teaching that cytotoxic agents, including agents of the same class, may display cooperative or non-cooperative anti-

cancer activity in combination with 1MT (Muller et al, p. 315, Table 1, provided by Applicant), one of ordinary skill in the art would not reasonably expect the synergistic effect of the instantly claimed method on breast cancer to correlate to a synergistic effect in other species of cancer, let alone cancer as a genus.

Applicant argues that the treatment of cancer with combination of 1MT and a chemotherapy agent would reasonably be expected to result in an unexpected synergistic activity across the entire breadth of claim 57. Specifically, Applicant argues that 1MT demonstrated synergy with four different chemotherapy agents of different classes (cisplatin, doxorubicin, paclitaxel and cyclophosphamide) in the treatment of breast cancer and that some of these agents have demonstrated activity in other cancer types. This is found unpersuasive, because as noted above, 1MT has failed to demonstrate synergy with six different chemotherapy agents of different classes (5-FU, methotrexate, vinblastine, FTI, rapamycin and tetrathiomolybdate) in the treatment of cancer ((Muller et al, p. 315, Table 1, provided by Applicant), providing further evidence that one of ordinary skill in the art would not reasonably expect the synergy to correlate to synergy with other agents and in other species of cancer.

Claim Objections

Claim 66 is objected to as being dependent upon a rejected base claim, but may be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

Claims 38-40, 43-47, 55 and 56 (i.e. claims drawn to the administration of the elected specie of compound, methyl-TH-DL-Trp) are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628